

REMARKS/ARGUMENTS

Favorable reconsideration of this application as presently amended and in light of the following discussion is respectfully requested.

Claims 1, 2, and 4-31 are now pending in this application. Claims 1, 15, and 16 are herein amended.

In the outstanding Office Action, claims 1, 2, and 4-31 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,652,450. Claims 1, 2, and 4-31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 1, 2, 4-8, 13-16, 19, 20, and 26-29 are rejected under 35 U.S.C. § 102(b) as being anticipated by Silvestrini, U.S. Patent No. 4,979,956. Claims 1, 2, 4-8, 13-16, and 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Tihon et al, U.S. Patent No. 6,042,536. Claims 9 and 10 are rejected under 35 U.S.C. § 103(a) as being obvious over Silvestrini. Claims 9 and 10 are rejected under 35 U.S.C. § 103(a) as being obvious over Tihon. Claim 17 is rejected under 35 U.S.C. § 103(a) as being obvious over Tihon and further in view of Trabucco, U.S. Patent No. 6,306,079. Claim 21 is rejected under 35 U.S.C. § 103(a) as being obvious over Tihon and further in view of Berger, U.S. Patent No. 6,638,210. The Office also objects to the drawings, the specification, and an information disclosure statement.

Amended claim 1 is directed to a sling for treating urinary incontinence in a patient. The sling comprises first and second major surfaces, a pair of end portions, a support portion, and a repositioning means. The support portion is for placement in a therapeutically effective position relative to a physiological environment intended to be supported, and has an axially elongate mesh and a pair of ends. The repositioning means is associated with the sling, and is for transferring sling tightening or sling loosening forces along the sling to afford effective, permanent repositioning of the sling without adversely affecting the therapeutic effect of the

sling. The repositioning means is manually adjustable. Claims 2 and 4-31 all depend directly or indirectly from claim 1.

Claims 1, 2, 4-8, 13-16, 19, 20, and 26-29 are rejected under 35 U.S.C. § 102(b) as being anticipated by Silvestrini. These rejections are respectfully traversed, as the Office has failed to state a *prima facie* case of anticipation.

Silvestrini discloses a device for use in repairing severed connective tissue of tendons and ligaments by approximating the severed ends of that tissue. The tissue ends are brought together by use of an elongated body. The body is sized and configured for enclosure within the abutting tissue ends, and it is adapted at both ends to be connected to at least one needle bearing suture. The suture is incorporated into substantially the length of the body. The Office asserts that Silvestrini discloses a support portion, a pair of end portions, and a repositioning means. However, such is not the case. The body of the Silvestrini has two ends, but it is not a support portion. Simply put, there is no teaching in Silvestrini that the body of the device supports anything.

Further, the suture of Silvestrini does not function in any way similar to the repositioning means of the present invention, and there is no teaching that it can function in such a way. The manually adjustable repositioning means of the present invention transfers sling tightening or sling loosening forces along the sling to afford effective, permanent repositioning of the sling without adversely affecting the therapeutic effect of the sling. Contrarily, the suture of the Silvestrini device serves to merely pull the severed ends of certain body tissues together. The body of the Silvestrini device is not repositioned. If anything is “repositioned”, it is the ends of the severed tissue. Further, specific embodiments of the Silvestrini device make it clear that movement of the body of the device in a way similar to the repositioning in the present invention is to be avoided. A preferred form of the device includes lock stitching of the suture at the ends of the body in order to prevent

“bunching during insertion into tissue”. *See Silvestrini*, col. 4, lines 30-33. The movement of the suture, with its concurrent movement of the body of the structure, is avoided by placement of the lock sutures. Similar structure would, in fact, prevent the repositioning means of the present invention from functioning as designed.

Finally, with regard to *Silvestrini*, there is no teaching or suggestion that the tightening and loosening forces controlled by the suture of the device are amenable to the manual adjustment of the suture. The device is placed into slots created in the severed ends of the tissue, half in one end, and the opposing end of the severed tissue is essentially pulled over the other half of the device. No manual adjustment of the tension or location of the device through the manual adjustment of the suture is taught or suggested. Failing to disclose either a support body or a repositioning means as found in the present invention, *Silvestrini* can not anticipate the present invention. As such, Applicants’ respectfully request the withdrawal of this rejection of claim 1, as well as for the same rejections for the claims depending from claim 1.

Claims 1, 2, 4-8, 13-16, and 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Tihon*. These rejections are respectfully traversed, as the Office has failed to state a *prima facie* case of anticipation.

Tihon discloses a sling for the treatment of urinary incontinence by supporting the urethra and neck of the bladder. The sling includes a support made of a stretchable non-porous material to limit tissue integration into the support, first and second suture anchors positioned at opposite ends of the stretchable support; and sutures cooperating with said suture anchors to fix the stretchable support in place. As discussed above, the sling of the present application comprises first and second major surfaces, a pair of end portions, a support portion, and a repositioning means. The repositioning means is manually adjustable. It appears that *Tihon* discloses a sling with two end portions. The Office asserts that *Tihon*

also discloses a repositioning means. However, the structure the Office identifies as analogous to the repositioning means of the present application does not serve to transfer sling tightening or sling loosening forces along the sling to afford effective, permanent repositioning of the sling without adversely affecting the therapeutic effect of the sling. The structure in the Tihon device merely serves as a length limiting device. Further, no adjustment of the tension or location of the device through the manual adjustment of the length limiting string is taught or suggested by Tihon. Failing to disclose a repositioning means as found in the present invention, Tihon can not anticipate the present invention. As such, Applicants' respectfully request the withdrawal of this rejection of claim 1, as well as for the same rejections for the claims depending from claim 1.

Claims 9 and 10 are rejected under 35 U.S.C. § 103(a) as being obvious over Silvestrini. These rejections are respectfully traversed as the Office has failed to state a prima facie case of obviousness. As discussed above, Silvestrini neither discloses nor suggests a support body or a repositioning means as disclosed in claim 1 of the present application, from which claims 9 and 10 depend. Applicants' respectfully request the withdrawal of these rejections.

Claims 9 and 10 are rejected under 35 U.S.C. § 103(a) as being obvious over Tihon. These rejections are respectfully traversed as the Office has failed to state a prima facie case of obviousness. As discussed above, Tihon neither discloses nor suggests a repositioning means as disclosed in claim 1 of the present application, from which claims 9 and 10 depend. Applicants' respectfully request the withdrawal of these rejections.

Claim 17 is rejected under 35 U.S.C. § 103(a) as being obvious over Tihon and further in view of Trabucco. This rejection is respectfully traversed as the Office has failed to state a prima facie case of obviousness. As discussed above, Tihon neither discloses nor suggests a repositioning means as disclosed in claim 1 of the present application, from which,

from which claim 17 depends. Trabucco, likewise, does not disclose or suggest a repositioning means as found in the present invention. Applicants' respectfully request the withdrawal of this rejection.

Claim 21 is rejected under 35 U.S.C. § 103(a) as being obvious over Tihon and further in view of Berger. This rejection is respectfully traversed as the Office has failed to state a prima facie case of obviousness. As discussed above, Tihon neither discloses nor suggests a repositioning means as disclosed in claim 1 of the present application, from which claim 21 depends. Berger does not remedy this inadequacy. Applicants' respectfully request the withdrawal of this rejection.

Claims 1, 2, and 4-31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 1 is amended herein to correct the typographical error making the claim indefinite. Regarding the rejection of claims 15 and 16 as indefinite because of use of the phrase "combinations thereof" without setting forth the possible combinations, claim 15 and 16 are amended to put the claims in proper Markush claim format. Claims of this sort are clearly permitted under U.S. Patent Office practice. *See Manual of Patent Examining Procedure* § 2173.05(h). Further, the use of qualifying language, such "mixtures thereof" and "combinations thereof", to indicate the applicant's desire to claim such combinations of members of the Markush group, is long accepted practice. *See Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.*, 67 USPQ2d 1191, 1196-97 (Fed. Cir. 2003). Applicants respectfully request withdrawal of these rejections.

Claims 1, 2, and 4-31 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,652,450. This rejection is respectfully traversed, as the Office has not established a prima facie case of obviousness-type double patenting. Specifically, the Office has not provided any references or other information to support its allegation that the claims in the present application are

obvious variations of the claims in U.S. Patent No. 6,652,450. The Office must make a prima facie case of obviousness. Without this, a finding by the Office that the claims are obvious is legally insufficient. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Regarding the Information Disclosure Statements, a corrected copy of the IDS submitted on July 11, 2003, in which earlier inadvertent errors will be corrected, is being prepared and will be submitted shortly.

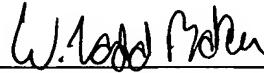
Regarding the objection to the specification, the specification is amended to provide for a more descriptive title. Two paragraphs are also amended. No new matter has been added. It is believed the Office's objections have been addressed.

Regarding the objection to the drawings, a replacement Figure 1B is herein submitted. This figure does not add new matter as it is supported in the specification at least in paragraph 0114 and claim 9. The new figure clearly shows the repositioning means comprising a plurality of filaments 66. In addition, replacement Figure 8C is herein submitted. This figure shows an example of a position adjustment member including at least one filament woven in the mesh and a portion of the mesh that is more tightly woven than the rest of the mesh. This figure does not add new matter as it is supported by the specification at least in paragraphs 0114 and 0115 and claims 8, 11, and 12. Finally, the Office objected that the handle of claim 31, in which the repositioning means comprises a handle situated in the support portion, was not shown. Applicant calls the Office's attention to paragraph 0129, describing the handle, and Fig. 6, in which the handle is shown by item 15. With the amended figures and the amended specification, it is believed the Office's objections have been addressed.

In light of the above discussion, the present application is believed to be in condition for allowance. An early and favorable action to that effect is respectfully requested.

Respectfully submitted,

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Application No. 10/616,925
Reply to Office Action of July 2, 2004

IN THE DRAWINGS

The attached sheets of drawings includes changes to Fig. 1B and Fig. 8C. These sheets replace the original sheets including Fig. 1B and 8C.

Attachment: Replacement Sheets